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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,810	07/22/2003	Wun Chey Sin	006539.00050	5281

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EXAMINER	
HALVORSON, MARK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,810	SIN ET AL.	
	Examiner	Art Unit	
	Mark Halvorson	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,12-14,21,27,32,33,35-37,44-46,53,59 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5, 12-14, 21, 27, 32, 33, 35-37, 44-46, 53, 59 and 64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1, 3-5, 12-14, 21, 27, 32, 33, 35-37, 44-46, 53, 59 and 64 are pending.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, drawn to a method for diagnosing a cancer in a mammal, comprising determining NMB gene copy number, classified in class 435, subclass 6.

II. Claims 4, 5, drawn to a method for inhibiting cancer or precancerous growth comprising contacting the tissue with an inhibitor that interact with NMB DNA or RNA, classified in class 514, subclass 44.

III. Claims 12, 13, drawn to a method for diagnosing a cancer in a mammal, comprising determining the level of NMB, classified in class 435, subclass 6.

IV. Claims 14, drawn to a method of administering siRNA to a patient wherein the siRNA interacts with the NMB gene or NMB mRNA transcript, classified in class 514, subclass 44.

V. Claims 21, 27,drawn to a method of screening a test molecule for NMB antagonist activity, classified in class 435, subclass 325.

VI. Claim 32 ,drawn to a method for selecting test molecules having a therapeutic effect in a patient, comprising measuring NMB mRNA or NMB expression levels, classified in class 514, subclass 44.

VII Claims 33, 35, drawn to a method for diagnosing a cancer in a mammal, comprising determining NMBR gene copy number, classified in class 435, subclass 6.

VIII. Claims 36, 37, drawn to a method for inhibiting cancer or precancerous growth comprising contacting the tissue with a inhibitor that interact with NMBR DNA or RNA, classified in class 514, subclass 44.

IX. Claims 44, 45, drawn to a method for diagnosing a cancer in a mammal, comprising determining the level of NMBR, classified in class 435, subclass 6.

X. Claims 46, drawn to a method of administering siRNA to a patient wherein the siRNA interacts with the NMBR gene or NMBR mRNA transcript, classified in class 514, subclass 44.

XI. Claims 53, 59, drawn to a method of screening a test molecule for NMBR antagonist activity, classified in class 435, subclass 325.

XII. Claim 64, drawn to a method for selecting test molecules having a therapeutic effect in a patient, comprising measuring NMBR mRNA or NMBR expression levels, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-XII are materially distinct methods that differ at least in objectives, method steps and reagents. Group I is drawn to a method for diagnosing a cancer in a mammal, comprising determining NMB gene copy number. Group II is drawn a method for inhibiting cancer or precancerous growth comprising contacting the tissue with a inhibitor that interact with NMB DNA or RNA. Group III is drawn to a method for diagnosing a cancer in a mammal, comprising determining the level of NMB. Group IV is drawn to a method of administering siRNA to a patient wherein the siRNA interacts with the NMB gene or NMB mRNA transcript. Group V is drawn to a method of screening a test molecule for NMB antagonist activity. Group VI is drawn to a method for selecting test molecules having a therapeutic effect in a patient, comprising measuring NMB mRNA or NMB expression levels. Group VII is drawn to a method for diagnosing a cancer in a mammal, comprising determining NMBR gene copy number. Group VIII is drawn a method for inhibiting cancer or precancerous growth comprising contacting the tissue with a inhibitor that interact with NMBR DNA or RNA. Group IX is drawn to a method for diagnosing a cancer in a mammal, comprising determining the level of NMBR. Group X is drawn to a method of administering siRNA to a patient wherein the siRNA interacts with the NMBR gene or NMBR mRNA transcript. Group XI is drawn to a method of screening a test molecule for NMBR antagonist activity. Group XII is drawn to method for selecting test molecules having a therapeutic effect in a patient, comprising measuring NMBR mRNA or NMBR expression levels Each of the groups employ different steps or different reagents to accomplish different objectives

that comprise different method steps. Searching all of the groups with all of the different objectives, method steps, and reagents would invoke a high burden of search.

SPECIES ELECTION

3. This application contains claims directed to the following patentably distinct species of the claimed invention.

Claims 3, 5, 35, 37 are drawn to a method using multiple types of cancer or tissue that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claims 3, 5, 35 and 37 are generic claims which include a Markush-type plurality of types of cancer or tissue. A Markush-type claim can include independent and distinct inventions.

(i). Groups I, VII are subject to election of at least one of the disclosed species.

Claims 3 and 35 are generic to a plurality of types of cancer, the types of cancer being (a) **breast** (b) **colon**, (c) **lung**, (d) **brain** or (e) **ovarian cancer**.

(ii). Group II is subject to election of at least one of the disclosed species.

Claim 5 is generic to a plurality of types of tissue, the types of tissue being (a) **breast** (b) **colon**, (c) **lung**, (d) **brain** or (e) **ovarian tissue**.

(iii). Groups VIII is subject to election of at least one of the disclosed species.

Claim 37 is generic to a plurality of types of tissue, the types of tissue being (a) **breast** (b) **colon**, or (c) **ovarian tissue**.

Claims 1, 4, 12, 33, 36, and 44 are drawn to a method using samples from different disease types that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claims 1, 4, 12, 33, 36, and 44 are generic claims which include a Markush-type plurality of types of disease types. A Markush-type claim can include independent and distinct inventions.

(iv). Groups I, II, III, VII, VIII, and IX are subject to election of at least one of the disclosed species.

Claims 1, 4, 12, 33, 36, and 44 are generic to a plurality of disease types, the disease types being (a) **cancer** (b) **precancerous growth**.

Claims 4, 14, 36, 46, are drawn to a method using different molecules that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claims 4, 14, 36, 46 are generic claims which include a Markush-type plurality of types of molecules. A Markush-type claim can include independent and distinct inventions.

(v). Groups II, IV, VIII, and X are subject to election of at least one of the disclosed species.

Claims 4, 14, 36, 46 are generic to a plurality of molecules, the molecules being (a) **DNA** or (b) **RNA**.

Claims 32 and 64, are drawn to a method using different molecules that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claims 32 and 64 are generic claims which include a Markush-type plurality of types of molecules. A Markush-type claim can include independent and distinct inventions.

(vi). Groups VI and XII are subject to election of at least one of the disclosed species.

Claims 32 and 64 are generic to a plurality of molecules, the molecules being (a) **mRNA** or (b) **protein**.

If applicant selects more than one species applicant must identify the combination of species to be examined.

4. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
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PRIMARY EXAMINER